INFORMATION AND COMMUNICATION SERVICES
NIH - TASK ORDER

TASK ORDER # NICS-FW001-

PART I - INITIATOR'S REQUEST

Name: **Mary Daum**
Phone- 301-594-7559 Fax- 301-496-9988

Address: 45 Center Drive, Bldg 45, Rm 4AS19

Agency-Billing Address: Accounts Payable, OFM, NIH
Bldg 31, Room B1B39
Bethesda, MD 20892-2045

B. PROPOSED PERIOD OF PERFORMANCE:
Project A: Award date – 5 months later
Project B: Feb 23, 2001 – June 28, 2001

C. TASK DESCRIPTION: (✓) Check here if an attachment is used.

The National Institute of Dental and Craniofacial Research (NIDCR) is currently developing new patient education publications on a) periodontal disease and b) oral cancer. To determine if these materials are understandable, relevant, attention-getting, credible, and acceptable to their target audiences, the Institute is seeking contract assistance to test these materials and to provide recommendations for modification of materials before they are printed. Additional information on the public's knowledge and perceptions of periodontal disease and oral cancer is also desired. Firms shall make proposals both on a firm-fixed price basis and on a labor-hour basis.

D. EVALUATION FACTORS

Evaluation factors for both projects A and B

a. Costs (20 points)
Contractors are to provide a line-item budget with a narrative justification for each line item. The contractor will be evaluated on the extent to which each line item is reasonable and consistent with the purpose and objectives of the task order.

b. Technical proposal (30 points)

Contractors are to provide a written proposal demonstrating an understanding of the task order requirements through a comprehensive description of the proposed approach, and the scheduling and assignment of tasks to experienced personnel. The technical proposal will be evaluated according to soundness, practicality, and feasibility of the written description.

c. Staffing and management (30 points)

Contractors are to provide a staffing plan to demonstrate an understanding of the labor requirements of the task order and a management plan that describes the contractor's approach to managing work and subcontract management, if applicable. As part of the staffing and management plan, the contractor shall summarize the relevant experience and skills of each of the individuals proposed for the task order. The summaries shall not exceed a quarter page. The summaries should highlight experience in oral health and/or chronic disease issues, experience with the proposed technical approach, experience in evaluation design and methodology, and experience and/or training in health education or health communication. These summaries are in lieu of full-length resumes.

d. Prior Experience (20 points)

Contractors are to provide quarter page descriptions of no more than four projects demonstrating the contractor's ability to execute the proposed technical approach and/or the contractor's experience with oral health and/or chronic disease issues and the design and evaluation of health education materials.

Reporting Requirements (for both projects A and B)

Draft and final versions of evaluation tools and reports will be shared in hard copy as well as Microsoft Word compatible electronic versions. It is expected that the contractor will work closely with NIDCR staff in the development and finalization of all plans and deliverables.

The contractor shall provide the NIDCR project staff with an electronic copy of task activities contained in the monthly report that is prepared for the project officer. This report shall include the amount of money expended to date and the money remaining by task.

In addition to the final reports, the contractor shall provide NIDCR with data products generated by the task order, such as audio tapes of the focus groups and completed interview forms.

E. RESPONSE DUE DATE: Five weeks after date of Amendment #3.

TO # NICS-_____ CONTRACT # 263-00-D-00___
PART II - CONTRACTOR'S REPLY :

Contractor:
Points of Contact:
Phone- Fax-
Address:

TOTAL ESTIMATED COST: (ATTACH BREAKDOWN)
TOTAL ESTIMATED NUMBER OF HOURS:
PROPOSED COMPLETION DATE:

FOR THE
CONTRACTOR:_____
Signature Date

PROJECT OFFICER'S RECOMMENDATION:

I ADJUDGE THE ABOVE PROPOSAL TO BE REASONABLE AND RECOMMEND THAT IT IS IN THE BEST INTEREST OF THE GOVERNMENT TO AWARD THIS TASK ORDER. MY REASON FOR SELECTING THIS CONTRACTOR IS ATTACHED.

Record of Call (ROC) # _____
(ATTACH OBLIGATING DOCUMENT IF AN ROC WILL NOT BE USED.)

RECOMMENDED:

_____
FAX # Signature - Project Officer Date

APPROVAL -

THE CONTRACTOR SHALL NOT EXCEED THE ESTIMATED LABOR HOURS OR ESTIMATED TASK ORDER AMOUNT WITHOUT THE WRITTEN APPROVAL OF THE CONTRACTING OFFICER

FOR THE GOVERNMENT:

APPROVED:_____
Signature - Contracting Officer Date

PROJECT A: PERIODONTAL DISEASE

Backgound

Periodontal (gum) diseases are a group of diseases characterized by inflammation of the gums and sometimes the loss of attachment of the periodontal ligament and the bony support of the tooth.

What causes periodontal diseases?

Our mouths are full of bacteria. These bacteria, along with mucus and other particles, constantly form a sticky, colorless "plaque" on teeth. Plaque that is not removed can harden and form bacteria-harboring "tartar" that brushing doesn't clean. Only a professional cleaning by a dentist or dental hygienist can remove tartar.

Gingivitis
The longer plaque and tartar are on teeth, the more harmful they become to teeth and gums. The harmful bacteria in tartar cause gum inflammation called "gingivitis." Gingivitis is characterized by red, swollen gums that bleed easily. It is a mild form of gum disease that can usually be reversed with regular brushing, flossing, and cleaning by a dentist or dental hygienist. This form of gum disease *does not* include any loss of bone and tissue that hold teeth in place.

Periodontitis
Periodontitis is also an inflammatory condition of the gingival tissues, but unlike gingivitis, it includes the loss of attachment of connective tissues and the bony support of the tooth (Genco, 1990). Periodontitis is thought to develop as an extension of gingivitis, although only a few gingivitis sites make this transition, and the mechanisms by which they do so are not well understood (Page, 1986).

In periodontitis, gums pull away from the teeth and form "pockets" that are infected. The body's immune system fights the bacteria as the plaque spreads and grows below the gum line. Enzymes fighting the infection actually start to break down the bones and connective tissue that hold teeth in place. If not treated, the bones, gums, and connective tissue that support the teeth will wear down. The teeth may finally become loose and fall out.

Today, the ‘burst’ theory of periodontitis is widely accepted. This theory states that periodontitis progresses in a series of relatively short ‘bursts’ or rapid tissue destruction, followed by some tissue repair and with long periods of remission (Listgarten, 1986). This view differs from the old “linear” model of periodontitis -- gingivitis inevitably progresses to periodontitis; untreated periodontitis progresses slowly but steadily, in a linear fashion, over time (Williams, 1998).

Moderate or Severe Periodontitis?
There are no generally accepted definitions of severe or moderate periodontitis, terms used in clinical practice. Researchers and clinicians use radiographs of bone loss, plus clinical measures of loss of periodontal attachment (LPA), pocket depth, gingival bleeding, and presence of plaque and calculus to diagnosis the severity of periodontal diseases (Burt and Ecklund, 1999). However, there is moderate agreement in the literature that LPA of 6 mm or more is a reasonable cutoff point between serious and moderate periodontitis. The term “moderate” is usually applied to LPA of 4 to 5 mm or less (Burt and Ecklund, 1999).

Prevalence

- Over 90 percent of people 13 years and older show some evidence of periodontal diseases (includes gingivitis) (Brown, 1996)
- Mild gingivitis is common, as is mild-to-moderate periodontitis: Most adults exhibit some loss of bony support and loss of attachment while still maintaining a functioning dentition. (Burt and Eklund, 1999)
- The prevalence and extent of periodontal attachment loss increases with age. Moderate attachment loss of 3-4 mm is found in 30 percent of 25 -34-year-olds, 63 percent of 45 -54-year-olds, and 80 percent of people over 65. (Brown, 1996)
- Only a small proportion of persons (about 15 percent) aged 13 and older have more severe periodontal destruction – attachment loss of 5mm or more. (Brown, 1996)
- Overall, women have better periodontal health than men (Brown, 1996)
- Whites have fewer periodontal problems than do blacks or Mexican Americans (Brown, 1996)

Risk Factors

- Tobacco use**.** Cigarette smoking can make you more vulnerable to gum disease.
- Hormonal changes. Changes in hormone levels are part of puberty, pregnancy and menopause. These changes can make gums more sensitive and make it easier for gum disease to start.
- Diabetes. People with diabetes are at higher risk for developing infections, including periodontal diseases. Also, these infections can reduce the body's ability to use insulin, which may make diabetes harder to control.
- Stress. Research shows that stress can make it more difficult for our bodies to fight infection, including periodontal disease.
- Medications. Some drugs, such as oral contraceptives, antidepressants, and some heart medicines can affect oral health because they lessen the flow of saliva. (Saliva has a protective effect on teeth and gums.)
- Grinding teeth. Clenching or grinding teeth puts extra force on teeth and can make gum disease worse.
- Poor nutrition. A poor diet can make it difficult for the body to fight infection.
- Illnesses. Diseases like cancer or AIDS can also affect the health of gums.

Treatments

These treatments are used in various combinations depending on the severity of the disease.

1. **Scaling and root planing.** Scaling means scraping off the tartar from above and below the gum line. Root planing gets rid of rough spots on the tooth root where the germs gather.
2. **Medications.** These medications are sometimes used in combination with scaling and root planing: antibiotic "chip", antibiotic gel, antibiotic fibers, all of which are placed in periodontal pockets. Also used are an antimicrobial mouthrinse and an enzyme suppressant.
3. **Surgery.** Gum Surgery might be necessary if the gum disease is advanced and includes bone loss around the teeth. "Flap" surgery, also called pocket depth reduction, involves lifting back the gums and removing the tartar. The gums are then sewn back

in place so that the tissue fits snugly around the tooth again. Other procedures that might be used include:

- Bone Grafting -- Natural or artificial bone may be grafted (placed) in areas of severe bone loss to provide the teeth with better support.
- Guided Tissue Regeneration -- After surgery, a mesh-like fabric is placed between grafted material and gum tissue to encourage bone and connective tissue to grow. The fabric dissolves over time.
- Soft Tissue Graft -- Tissue is taken from another part of the mouth and sewn into where it is needed around the teeth. This is done to cover and protect exposed tooth roots or to thicken very thin gum tissue.

Need for Consumer Pamphlet

NIDCR has determined from calls and letters to the NIDCR information office that there is a need for a concise, easy-to-understand pamphlet about periodontal diseases. The Office of Health Communication and Education (OCHE) at NIDCR now has drafted a pamphlet that describes periodontal diseases as well as the treatments currently available. It is now necessary to pretest the pamphlet with the target audience.

Description of the Work

Task 1. Meet with NIDCR OCHE program staff

The contractor will meet with program staff to familiarize themselves with the NIDCR and staff involved.

Task 2. Draft gatekeeper review interview guide

Because one of the anticipated channels for distributing the periodontal disease publication to the target audience will be dental clinicians, it is necessary to gain the opinions of practicing dentists, dental hygienists, and/or periodontists. The gatekeeper review tool should answer, but not be limited to, the following questions:

- Based on what you know about your clients diagnosed with periodontitis, does this answer some or all of their questions about treating the disease?
- What do you feel are the main messages of the publication?
- Do you agree or disagree with the messages in the publication?
- Are there any facts that you feel are inaccurate?
- Is important information missing?
- How likely are you to use the publication as a patient education tool?

Task 3. Conduct gatekeeper interviews

NIDCR estimates that two pilot interviews and 9 in-depth interviews by phone will be needed. NIDCR will provide the contractor with contacts for recruiting all interviewees, and the contractor will set up the interviews, provide the interviewees with the draft publication, and conduct the interviews. The interviews may require long distance telephone calls.

Task 4. Develop summary report of gatekeeper review with suggested modifications to the publication

The contractor will provide a brief summary report of the findings from the gatekeeper interviews and recommendations for changes in the publication. After receiving input from NIDCR, the contactor will finalize the summary report and recommendations. NIDCR will implement the recommendations and develop a revised draft of the publication.

Task 5. Draft and finalize focus group guide for target audience testing

To determine if the publication is understandable, relevant, attention getting and credible with the target audience, the contractor will conduct at total of 3 focus groups with representative members of the target audience. Each of the three focus groups will consist of individuals who have been diagnosed with periodontal disease by a dentist or periodontist within the past year. The individuals will be fluent in English and between the ages of 35 and 55. The groups can be mixed in terms of gender and race.

Questions in the focus group guide will include but may not be limited to:

- Is the publication easy to understand?
- What do you think are the main messages of the publication?
- Does it address your questions about treating periodontitis?
- Will the publication help you make a decision about treatment or help you discuss treatment options with your dental clinician?
- What are your preferences in layout, design, and format?

In addition to information on the education materials, the focus groups should explore the public's knowledge of periodontal disease, their perception of the problem, attitudes about periodontal disease and oral health, and reasons for delays in beginning treatment once diagnosed with the disease.

Task 6. Recruit participants for focus group

The groups will take place in the Washington area or within an hour drive from the Washington, DC, area. For this project, NIDCR feels that recruitment through newspaper advertisements and advertisements at central locations frequented by the target audience are preferred over recruitment by phone using focus group databases.

Task 7. Conduct focus groups

The contractor will be responsible for organizing, coordinating the logistics of, and facilitating the focus groups. This includes securing an appropriate and qualified moderator.

Task 8. Develop report of all findings and final recommendation for modification of materials

The contractor will provide a detailed report of the all findings (i.e., gatekeeper review interviews and focus groups) in hard copy as well as Microsoft Word compatible electronic versions. The contractor shall first provide a draft report, and after final input from NIDCR,

20 copies of a final report. The report will include at least an executive summary, a section describing the evaluation methods, a section describing findings, and a section discussing recommendations for revising the publication. Appendices to the report should include the final moderator's guide, moderator top line reports, a sample of the publication that was tested, and any other tools or documents generated to collect data or report findings.

Deliverables (and suggested timeline)

Week (from date of task award)	**Task**
1	Meeting with NIDCR program staff
2-3	Draft gatekeeper interview guide
4	Final gatekeeper interview guide
4-5	Conduct gatekeeper interviews
6-7	Draft summary of gatekeeper findings and recommendations for changes to health education material
8-9	Final summary of gatekeeper findings and recommendations for changes to health education material
10-11	Draft focus group guide and focus group screener
12	Finalize focus group guide and screener
13	Conduct focus groups
17	Draft final report of findings
20	Final report of findings

PROJECT B: ORAL CANCER

Background

The American Cancer Society estimated that in 1999, 29,800 new cases of oral cancer were diagnosed and 8,100 people died of oral cancer (ACS, 1999). While oral cancer is less common than many cancers, the survival rates associated with the disease are cause for concern. The five-year survival rate for all stages of oral cancer is 54 percent, and the 10-year rate is 46 percent (ACS 1998, Ries, 2000). These survival rates are significantly lower than that of many more common cancers including breast cancer, colorectal cancer, lymphoma, prostate, and skin cancer.

Incidence of oral cancer differs by sex, race/ethnicity, and age. Between 1990 and 1997 more than twice as many men (15.1 per 100,000) were diagnosed with oral cancer than women (5.9 per 100,000) (Ries, et al., 2000). While men are still more likely than women to be diagnosed with oral cancer, note that this is a significant change from 1950, when the ratio of male to female diagnosis was 6:1. The changing ratio may be a result of changing smoking patterns over the past three decades, or the fact that oral cancer is related to age and women over age 65 outnumber older men by 50 percent (CDC, 1998).

Oral cancer incidence is higher among African Americans, particularly African American men compared to non-Hispanic whites. (NCI, 2000; ACS, 1999; Ries, et al., 2000). Between 1990 and 1997 African American men experienced an incidence rate of 20.3 per 100,000 versus an incidence rate of 15.4 in white non-Hispanic men. In general, the overall incidence rate among Asian/Pacific Islanders is lower than incidence rates of all other races and ethnicities (Ries, et al., 2000), but Asian/Pacific Islander men, particularly Hawaiian and Vietnamese men, have incidence rates higher than the norm for Asian/Pacific Islanders and slightly higher than the overall, all races/ethnicities incidence rate of 10.1 per 100,000 (Miller, et al., 1996).

Oral cancer incidence increases with age, with 95 percent of all oral cancer occurring in individuals over age 45 (CDC, 1996). However, the disease tends to affect black men at younger ages than men in other race or ethnicity groups. Among African American men, oral cancer incidence peaks a full two decades earlier than incidence in white men (Table 2). A 1993-97 SEER report shows that for African American men oral cancer incidence peaks between ages 60-64 at 85.6 per 100,000, while for white men the peak is a full two decades later, between the ages of 80-84 at 76.6 per 100,000 (Ries, et al., 2000). Compared to 1988-1992 SEER data, the difference in age at peak incidence holds true, though the peaks in this earlier time period occurred at slightly younger ages -- 55-59 for white men and 75-79 for black men. Among Asian/Pacific Islanders incidence begins to increase in the 55 to 69 age range, with peak incidence occurring after age 70 (Miller, et al., 1999).

Oral cancer is largely a preventable disease. Most cases can be linked to use of tobacco and/or alcohol. Recognized major risk factors for oral cancer are as follows:

- **Using tobacco products**. Using tobacco products in the form of cigarettes, cigars, pipes, smokeless tobacco (snuff and chewing tobacco) has been identified as the primary risk factor in 75 percent of oral cancers in the United States (CDC, 1998). According to the American Cancer Society Cancer Prevention study, the risk for oral cancer in a male smoker is 27.7 times greater than that of a male who has never smoked. Among women who smoke, the risk was 6 times greater than that of women who have never smoked. The American Cancer Society's Cancer Prevention Study also estimated the risk of dying from oral cancer. The mortality risk for oral cancer

among those who smoke cigarettes versus those who have never smoked was estimated to be between 6:1 and 10:1. Moreover, there appears to be a dose response relationship – the more cigarettes consumed daily and the more years smoked, the greater the risk for death from oral cancer. (CDC, 1996).

Pipe and cigar use have also been consistently linked to increased oral cancer incidence and mortality. The risks from pipe and cigar use are similar to those associated with cigarette use (CDC, 1996). Spit tobacco has also been demonstrated to have a causal link to oral cancer, contributing to at least a four-fold increase in relative risk, depending on duration of usage (CDC, 1996).

- **Using alcohol.** Most patients with oropharyngeal cancers drink alcohol, but until recently, identifying alcohol as an independent risk factor has been difficult (CDC, 1996, 1998). Recent studies indicate that alcohol use alone has a carcinogenic effect similar to that of tobacco alone and that alcohol exhibits a dose-response relationship where the more a person drinks the higher the risk (Blot, 1999). All forms of alcohol (beer, hard liquor, and wine) have been associated with oral cancer, but higher risks have been attributed to hard liquor and wine intake (CDC, 1996).

- **Using both alcohol and tobacco.** There is evidence of a synergistic effect between tobacco and alcohol, with use of both significantly increasing risk for the disease. (CDC, 1996; Blot, 1999). While the odds ratio for oral cancer for a male heavy smoker is 5.8 and the odds ratio for a male heavy drinker is 7.4, for a male heavy smoker and heavy drinker the odds ratio is 38. For women who smoke and drink heavily the odds ratio is 100 (CDC, 1996).

- **Exposure to sunlight.** Excessive exposure to sunlight without sunscreen is associated with cancers of the lips. Cancers caused by exposure to sunlight are more common in people with fair skin than people with darker pigmentation. (CDC, 1996).

Inadequate intake of dietary fiber has also been associated with oral cancer, but tobacco and alcohol use far outweigh diet as a risk factor for oral cancer. Viruses and their interactions with oncogenes and immunosuppression are under investigation for their links to oral cancer. At present, there seems to be a positive link between a subset of head and neck cancers and the sexually transmitted human papillomavirus (Gillison, et al., 2000). However, gaps in knowledge prevent making any conclusions at this time about the risks posed by viruses and immunosuppression. While some have implicated poor oral hygiene and use of mouthwash as risk factors, there is insufficient evidence to substantiate these claims. (CDC, 1996).

Knowledge of risk factors and signs and symptoms for oral cancer is essential for reducing oral cancer incidence and mortality. This knowledge may encourage those at risk for oral cancer to modify their behaviors before they have developed the condition, and to seek professional help if signs and symptoms of oral cancer are present.

The public should also be aware of the importance of early detection of oral cancer, the role of a visual and tactile examination of the oral cavity for early detection, and the steps of such an exam. Because of the significant morbidity and mortality associated with the diagnosis of oral cancer at advanced stages, the U.S. Preventive Services Task Force recommends that clinicians include a careful examination for oral cancer in asymptomatic individuals who use tobacco or alcohol.

The 1990 National Health Interview Survey, Health Promotion and Disease Prevention Supplement, included four questions about oral cancers. This study revealed that the U.S.

adult public is not well informed about signs of oral cancers. In addition, despite the fact that dentists and dental hygienists report that they generally perform oral cancer exams, the 1992 National Center for Health Statistics (NCHS) Cancer Supplement Survey found that only 14% of the public reported that they had ever been examined for oral cancers and 7% reported that they had had the examination within the past year. Lack of awareness of oral cancer and lack of familiarity with oral exam procedures may in part explain these low percentages.

To help increase awareness of oral cancer, risk factors, signs and symptoms of oral cancer, the importance of early detection, and the oral cancer examination, NIDCR has drafted a set of patient education pamphlets for distribution through private dental practices, dental clinics, medical offices, health fairs, etc. These materials have been tested with and modified based on feedback from both dentists and dental hygienists and now need to be tested with a diverse sample of the general public.

Description of the Work

Task 1. Meet with NIDCR Office of Communications and Health Education staff

The contractors will meet early in the project with program staff to familiarize themselves with the NIDCR and staff involved.

Task 2. Draft interview questionnaire

In addition to initial screening questions about age and past/present tobacco use, the types of questions to be developed and asked may include but are not limited to:

- Do you have medical insurance? Have you seen a physician within the past 12 months?
- Do you have dental insurance? Have you seen a dentist or dental hygienist within the past 12 months? If yes, what are the reasons? If no, why not?
- Do you drink alcoholic beverages (beer, wine, hard liquor)? Have you ever used …
- Have you ever had an oral cancer exam? Have you or has anyone in your family ever had oral cancer?
- What is the main message of the pamphlet(s)?
- Is this message relevant/important to you? Why/why not?
- What would motivate you to talk to a health care provider about oral cancer and/or your risk of oral cancer?
- How much of the information was new to you?
- Are the materials easy to understand? Do they address all consumer questions?
- Where should the materials be distributed/displayed?

Task 3. Pilot questionnaire

NIDCR estimates that 10 pilot interviews with a subset of the target audience will be needed. NIDCR will provide specific recommendations for what types of people should be interviewed; the contractor will be responsible for recruitment of interviewees.

Task 4. Modify questionnaire based on pilot test and feedback from NIDCR

Two to three revisions of the questionnaire may be required.

Task 5. Identify potential sites for central location intercept interviews

The contractor will be responsible for organizing all interview logistics, including identification of interview sites, securing interviewers, etc. Potential sites include malls and/or home improvement centers. Local sites (within an hour drive of NIH) are preferred as NIDCR is currently conducting a pilot oral cancer education program in Maryland.

Task 6. Conduct central location intercept interviews

Interviews should be conducted with a total of 400-500 tobacco users (past or present users) over age 40. The total interview sample should be approximately 2/3 men, 1/3 women and represent the general population in terms of race/ethnicity. All interviewees will be fluent in English. Persons with medical and/or dental insurance as well as persons without medical and/or dental insurance should be interviewed.

Task 7. Analysis of central location intercept interviews

The contractor shall propose a plan for analyzing the data obtained from the interviews.

Task 8. Develop summary report on findings and recommendations for modification of materials

The contractor will provide a detailed report of all findings (i.e. pilot and central location intercept interviews) in hard copy as well as Microsoft Word compatible electronic versions. The contractor shall first provide a draft report and after final input from NIDCR, 20 copies of a final report. The report will include at executive summary, a section describing the evaluation methods, a section describing findings, and a section discussing recommendations for revising the publication. Appendices to the report should include the interview questionnaire and sample of the publications tested.

Deliverables (and suggested timeline)

Week (from date of task award)	**Task**
1-4	Meet with NIDCR program staff
3-4	Draft interview questionnaire
5-6	Pilot interview questionnaire
7	Modify questionnaire based on pilot test and feedback from NIDCR

8-11	Upon approval of final questionnaire by NIDCR program staff, conduct central location intercept interviews
12-13	Prepare preliminary findings for presentation to NIDCR program staff
14	Finalize findings and revise according to program input
15	Submit final report to NIDCR program staff

References

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